DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 16, 2014

Given Imaging, Ltd.
Hila Debby
Director, Clinical & Regulatory
2 Hacarmel Street
New Industrial Park, PO Box 258
Yoqneam 20692
Israel

Re: K140284
Trade/Device Name: Given PillCam UGI capsule endoscopy system
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated: November 11, 2014
Received: December 15, 2014

Dear Hila Debby,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140284

Device Name: Given PillCam UGI capsule endoscopy system

Indications for Use:

The PillCam UGI capsule endoscopy system is intended for visualization of the upper gastrointestinal tract (esophagus, stomach, duodenum). It may be used for visualization of blood in the upper gastrointestinal tract (esophagus, stomach, duodenum) in patients who are hemodynamically stable and at least18 years of age.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

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Establishment Registration Number:	9710107
Date Prepared:	January 30, 2014
Device Trade Name(s):	Given® PillCam® UGI capsule endoscopy system
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system
Classification:	Regulation No: 876.1300, Class: II Panel: Gastroenterology/Urology NSI– System, Imaging, Esophageal, Wireless, Capsule NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule
Predicate Device(s):	• Given Diagnostic System with PillCam ESO 2 capsule (K071153) • Given PillCam Platform System with RAPID 6.5 and Given PillCam Platform with ESO 3 capsule (K103025) • Given PillCam® SB 3 capsule endoscopy system (K123864) • Given PillCam® COLON 2 capsule endoscopy system (K123666)

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General Device Description:

The Given PillCam Endoscopy system is comprised of four main subsystems; (1) the ingestible PillCam capsule, (2) the DR 3 PillCam Recorder, (3) the RAPID software, and (4) the Given Workstation and Accessories.

1. *Ingestible PillCam Capsule*
   The disposable, ingestible PillCam Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via a RF communication channel to the PillCam Recorder located outside the body.

2. *DR 3 PillCam Recorder*
   The DR 3 PillCam Recorder is an external receiving/recording unit that receives and stores the acquired images from the capsule.

3. *RAPID Software*
   The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the PillCam Recorder to create a RAPID video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms.
   RAPID 8.0 supports PillCam capsule endoscopy of the GI tract with all PillCam video capsules. In addition, RAPID 8.0 supports PillCam Recorder DR 2C and PillCam Recorder DR 3.

4. *Given Workstation and Accessories*
   The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. The PillCam Recorder is an external receiving/recording unit that receives acquired images from the capsule. The Sensor Array receives data from the PillCam capsule and transfers the data to the PillCam Recorder. Other accessories include a flat panel LCD monitor, a high-capacity mass storage device, and a high-capacity USB portable storage device.

Indication for use:

The PillCam UGI capsule endoscopy system is intended for visualization of the upper gastrointestinal tract (esophagus, stomach, duodenum). It may be used for visualization of blood in the upper gastrointestinal tract (esophagus, stomach, duodenum) in patients who are hemodynamically stable and at least18 years of age.

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Technological Characteristics:	The technological characteristics are similar to the predicate devices (ESO 2, ESO 3 and COLON 2 capsules). There are two modifications compared to the ESO 2 and ESO 3 capsules that are listed in Section 12 of this submission. However, it may be concluded from the Substantial Equivalence Summary that none of the presented changes raise any new safety issues. These two modifications have been made in order to achieve better coverage of the upper GI tissue. The first modification is the prolonged operation time. The second modification is the adaptive frame rate [35 frames per second (fps) in the first 10 minutes and 18 frames per second (fps) in the remaining 80 minutes]. No new safety issues were raised due to the proposed design.
Optical Features	4 white LEDs per optical head are used as the UGI capsule illumination source. The Field of view is 172° (ISO 9600-3) and the Effective Visibility distance is set to 0-30mm.
Bench testing:	Since PillCam UGI capsule and the COLON 2 capsule predicate device are identical in terms of external components and technology, the biting test and pH resistance test for the predicate device are applicable for PillCam UGI capsules as well. In addition optical resolution test results demonstrate that different pH environments do not affect the optical performance of the PillCam capsule, specifically the image quality.
Performance Data:	The device meets the guidance entitled "*Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA* dated November 28, 2001. The proposed changes in this submission do not raise new performance or safety issues.
Conclusion:	Based on the technological characteristics of the devices, Given Imaging Ltd. believes that the PillCam UGI capsule endoscopy system and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.